UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,452	07/31/2001	Sun Ai Raillard	02-107410US	4651

30560 7590 12/18/2002

MAXYGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
515 GALVESTON DRIVE
RED WOOD CITY, CA 94063

EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/18/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/920,452	Applicant(s) RAILLARD ET AL.	
	Examiner Carolyn L Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on th cov r sheet with the correspondenc addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-87* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-59 and 84, drawn to a method for producing a nucleotide incorporating enzyme that incorporates a non-natural or rare nucleotide analogue, classified in class 435, subclasses 69.1 and 91.1. If this Group is elected, then all **four** of the below summarized specie elections and subspecie election are also required.

II. Claims 60-73 and 85, drawn to a method for producing a nucleotide incorporating enzyme with increased tolerance to biological impurities, classified in class 435, subclass 68.1.

III. Claims 74-81, drawn to a nucleotide incorporating enzyme variant and kit, classified in class 435, subclass 183. If this Group is elected, then all **four** of the below summarized specie elections and subspecie election are also required.

IV. Claims 82-83, drawn to an integrated system comprising a non-natural nucleotide analogue, a nucleotide incorporating enzyme variant and a detector, classified in class 702, subclass 19, respectively. If this Group is elected, then all **four** of the below summarized specie elections and subspecie election are also required.

V. Claims 86-87, drawn to a method for identifying a nucleotide incorporating enzyme with a desired property, classified in class 435, subclass 6. If this Group is elected, then **one** of the below summarized specie election (last one mentioned) is also required.

Specie Election Requirements for Groups I, III, IV, and V:

This application contains claims directed to the following patentably distinct species of the claimed invention:

First Specie Election Requirement (for Groups I, III, and IV):

Specie A: a nucleotide analogue which is a nucleotide derivatized with a methyl group

Specie B: a nucleotide analogue which is a nucleotide derivatized with a nitrile group

Specie C: a nucleotide analogue which is a nucleotide comprising a fluorescent label

Specie D: a nucleotide analogue which is a nucleotide comprising a ribose or deoxyribose analogue

Specie E: a nucleotide analogue which is a nucleotide comprising an unnatural glycosidic linkage to a base

Second Specie Election Requirement (for Groups I, III, and IV):

Specie F: a nucleotide incorporating enzyme which is a nucleic acid polymerase

Specie G: a nucleotide incorporating enzyme which is a terminal transferase

Specie H: a nucleotide incorporating enzyme which is a ligase

Specie I: a nucleotide incorporating enzyme which is a telomerase

If Specie F is elected, then the following **Sub-Specie** Election is required:

Subspecie F-1: a nucleic acid polymerase which is a DNA dependent DNA polymerase

Subspecie F-2: a nucleic acid polymerase which is an RNA dependent DNA polymerase

Subspecie F-3: a nucleic acid polymerase which is an DNA dependent RNA polymerase

Subspecie F-4: a nucleic acid polymerase which is an RNA dependent RNA polymerase

Third Specie Election Requirement (for Groups I, III, and IV):

Specie J: identifying a nucleotide incorporating enzyme variant by optical spectroscopy

Specie K: identifying a nucleotide incorporating enzyme variant by fluorescent spectroscopy

Specie L: identifying a nucleotide incorporating enzyme variant by radiometry

Specie M: identifying a nucleotide incorporating enzyme variant by chromatography

Specie N: identifying a nucleotide incorporating enzyme variant by gel electrophoresis

Specie O: identifying a nucleotide incorporating enzyme variant by capillary electrophoresis

Specie P: identifying a nucleotide incorporating enzyme variant by streptavidin binding

Specie Q: identifying a nucleotide incorporating enzyme variant by hybridization

Specie R: identifying a nucleotide incorporating enzyme variant by fluorescent resonance energy transfer

Specie S: identifying a nucleotide incorporating enzyme variant by fluorescent polarization

Specie T: identifying a nucleotide incorporating enzyme variant by pyrophosphate detection

Fourth Specie Election Requirement (for Groups I, III, IV, and V):

Specie U: a desired property which is thermostability

Specie V: a desired property which is evenness of nucleotide incorporation

Specie W: a desired property which is efficient terminal transferase activity

Specie X: a desired property which is low fidelity

Specie Y: a desired property which is high fidelity

Specie Z: a desired property which is processivity

Specie AA: a desired property which is strand-displacement activity

Specie BB: a desired property which is nick translation activity

Specie CC: a desired property which is exchange reaction

Specie DD: a desired property which is cation requirement

Specie EE: a desired property which is modulation of activity by cation

Specie FF: a desired property which is sulfhydral reagent requirement

Specie GG: a desired property which is shelf life

Specie HH: a desired property which is salt tolerance

Specie II: a desired property which is organic solvent tolerance

Specie JJ: a desired property which is mechanical stress tolerance

Specie KK: a desired property which is tolerance to impurities

Specie LL: a desired property which is altered pH dependence

Specie MM: a desired property which is altered dependence on buffer conditions

Specie NN: a desired property which is template composition

Specie OO: a desired property which is primer composition

Specie PP: a desired property which is improved stability

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims in Groups I, III, IV, and V are generic to the above species.

The distinctness or independence of Species A through E is because they are based on nucleotides with critically different features. The critical feature of Specie A is a methyl group. The critical feature of Specie B is a nitrile group. The critical feature of Specie C is a fluorescent label. The critical feature of Specie D is a ribose or deoxyribose analogue. The critical feature of Specie E is an unnatural glycosidic linkage to a base.

The distinctness or independence of Species F through I is because they are based on nucleotide incorporating enzymes with critically different features. The critical feature of Specie F is a nucleic acid polymerase. The critical feature of Specie G is a terminal transferase. The critical feature of Specie H is a ligase. The critical feature of Specie I is a telomerase. Subspecies of Specie F (F-1 through F-4) are further deemed distinct or independent because they are based on polymerases with critically different features. The critical feature of Specie F-1 is a DNA dependent DNA polymerase. The critical feature of Specie F-2 is an RNA dependent DNA polymerase. The critical feature of Specie F-3 is a DNA dependent RNA polymerase. The critical feature of Specie F-4 is an RNA dependent RNA polymerase.

The distinctness or independence of Species J through T is because they are based on different unrelated techniques using different protocols.

The distinctness or independence of Species U through PP is because they are based on properties which are unrelated which do not require any other mentioned property.

The completely separate chemical and entity types of the above-mentioned species are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of

any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the above mentioned species are independent and/or distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

These groups are distinct, each from the other because of the following reasons:

Inventions in Groups I-V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case nucleotide incorporating enzyme variant of Group III may be utilized in distinct usages as needed in Group I for a method of producing a nucleotide incorporating enzyme that incorporates a non-natural or rare nucleotide analogue, in a method of producing a nucleotide incorporating enzyme with increase tolerance to biological impurities as in Group II, for use in an integrated system as in Group IV, in a method for identifying a nucleotide incorporating enzyme with a desired property, or alternatively, in making antibodies. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 9, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER